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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,721	10/15/2003	James K. Liao	B0801.70316US01	1754

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WOLF GREENFIELD & SACKS, PC  
FEDERAL RESERVE PLAZA  
600 ATLANTIC AVENUE  
BOSTON, MA 02210-2206

EXAMINER

HUYNH, CARLIC K

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/688,721

**Applicant(s)**

LIAO ET AL.

**Examiner**

Carlic K. Huynh

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-116 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-116 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-22, drawn to a method for increasing Nitric Oxide production, classified in class 514, subclass 330.
  - II. Claims 23-35, drawn to a method for attenuating the downregulation of Nitric Oxide production, classified in class 514, subclass 330.
  - III. Claims 36-49, drawn to a method for treating a nonhypercholesterolemic or nonhyperlipidemic subject with a cardiovascular disease or disorder, classified in class 514, subclass 330.
  - IV. Claims 50-64, drawn to a method for treating a subject with a cerebrovascular disease or disorder, classified in class 514, subclass 330.
  - V. Claims 65-78, drawn to a method for increasing cerebral blood flow, classified in class 514, subclass 330.
  - VI. Claims 79-89, drawn to a method for increasing Nitric Oxide Synthase activity, classified in class 514, subclass 330.
  - VII. Claims 90-101, drawn to a method for increasing Nitric Oxide production, classified in class 514, subclass 330.
  - VIII. Claims 102-116, drawn to a method for treating a subject with an inflammatory disease or disorder, classified in class 514, subclass 330.

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2. Inventions I-VIII are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions I-VIII have different designs, modes of operation, and effects because methods for increasing Nitric Oxide production of Invention I, for attenuating the downregulation of Nitric Oxide production of Invention II, for treating a nonhypercholesterolemic or nonhyperlipidemic subject with a cardiovascular disease or disorder of Invention III, for treating a subject with a cerebrovascular disease or disorder of Invention IV, for increasing cerebral blood flow of Invention V, for increasing Nitric Oxide Synthase activity of Invention VI, for increasing Nitric Oxide production of Invention VII, and for treating a subject with an inflammatory disease or disorder of Invention VII are not the same.

3. This application contains claims directed to the following patentably distinct species:

- (1) a single disclosed species of a HMG-CoA reductase inhibitor;
- (2) a single disclosed species of a cardiovascular disease or disorder;
- (3) a single disclosed species of a second agent;
- (4) a single disclosed species of a cerebrovascular disease or disorder; and
- (5) a single disclosed species of an inflammatory disease or disorder.

If Group I, or II, or III, or IV, or V, or VI, or VII, or VIII is elected, the applicant is required under 35 U.S.C. 121 to elect (1) a single disclosed species of a HMG-CoA reductase inhibitor for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. If Group III is elected, the applicant is required under 35 U.S.C.

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121 to elect (2) a single disclosed species of a cardiovascular disease or disorder for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. If Group III, or VI, or V, or VII, or VIII is elected, the applicant is required under 35 U.S.C. 121 to elect (3) a single disclosed species of a second agent for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. If Group IV is elected, the applicant is required under 35 U.S.C. 121 to elect (4) a single disclosed species of a cerebrovascular disease or disorder for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. If Group VIII is elected, the applicant is required under 35 U.S.C. 121 to elect (5) a single disclosed species of an inflammatory disease or disorder for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-6, 8-17, 19-26, 28-30, 32-40, 42-44, 46-55, 57-59, 61-69, 71-73, 75-80, 82-84, 86-91, 93-94, 97-107, 109-111, and 113-116 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP § 812.01). Therefore, since this restriction requirement is considered complex, a call to the attorney for telephone election was not made.

### ***Conclusion***

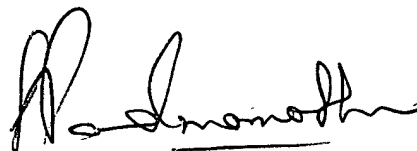
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER